UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 2 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DENISE M. ELSER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") submit this memorandum and attached exhibits in opposition to Plaintiffs' motion to exclude certain opinions and testimony of Denise Elser, M.D.

INTRODUCTION

Plaintiffs' motion to exclude certain expert testimony of Dr. Elser regarding tension-free vaginal tape ("TVT") and tension-free vaginal tape-obturator ("TVT-O") disregards and downplays her substantial clinical experience and qualifications, and completely ignores the extensive medical literature on which she comments in her report.

Plaintiffs seek to exclude her from testifying as to the adequacy of these devices' instructions for use ("IFU"), the safety and efficacy of TVT and TVT-O, and her own clinical experience with the devices. These arguments cannot be squared with this Court's prior rulings. Dr. Elser is well-qualified to offer the opinions that Plaintiffs seek to exclude:

- **Product Warnings:** Plaintiffs ignore Dr. Elser's extensive research of the scientific literature and experience as a surgeon and instructor; she is qualified to testify to: (a) the risks and complications known by surgeons to be common with pelvic surgeries, and, (b)

conversely, whether the complications and events unique to mesh are covered by the IFU. Those are the relevant facts under the applicable legal standard.

- **So-called "design" testimony:** Plaintiffs mischaracterize her testimony. Her opinion is not about the technical design history documents and whether they are in order. Instead, her opinions, from the perspective of a pelvic surgeon, are that in light of the actual design and material used in the devices when carried out in the surgical treatment of stress urinary incontinence, the devices are functional, have usefulness, perform as intended, and are safe, efficacious and are a desirable option for the surgical treatment of SUI. This and her opinions on biocompatibility are based on her review of the medical literature and her education, training and experience. She is fully qualified to give these opinions based on her many years as a surgeon and instructor and her review of the relevant medical literature.

- **Clinical Experience:** This Court has previously rejected attempts to exclude practitioners, like Dr. Elser, from offering testimony comparing their own experience to that in the medical literature.

For these reasons, as detailed further below, Plaintiffs' motion should be denied.

ARGUMENT

I. Standard for admissibility of expert opinion testimony.

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

II. Dr. Elser may testify, based on her work as a surgeon and instructor and her review of the medical literature and professional association statements, to the facts made relevant by the appropriate legal standard, i.e., the adverse event risks commonly known to pelvic floor surgeons, and to the risks said to be unique to mesh, i.e., erosion and extrusion, which are identified in the IFU.

The job of an expert witness is to provide the facts to which the court can apply the law. So long as the expert has supplied the facts in a form consistent with the law, she has done her job. It is not the expert's job to provide the Court with the law.

In fact, this Court has in the past excluded testimony which not only stated facts but also expressed a legal conclusion. *See In re Ethicon, Inc. Pelvic Repair Systems Product Liability*

Litigation (Lewis), 2014 WL 186872 (S.D. W. Va. 2014) at *20, *citing United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). And similarly the Court should exclude warnings testimony which fails to follow the appropriate legal standard. *See* Defendants Johnson & Johnson and Ethicon Inc.'s Memorandum in Support of Motion to Exclude Peggy Pence, Ph.D., [Doc. 2078], filed April 21, 2016 at pp. 6-7 (collecting authority).

The important question here is whether Dr. Elser's testimony was consistent with the law to be applied to the case, and not whether she herself could articulate the governing legal standard.

The legal standard. Dr. Elser's testimony on Defendants' IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety.

She looks to the IFU and warnings to "help[] delineate the steps of the procedure that might be unique to this procedure and to warn of any complications that might not be known to the average surgeon." (Ex. A, Elser 9/16/14 Dep. Tr. 36:3-14). So, in forming her opinions regarding Ethicon's IFU and warnings, she stated that her objective was to identify "what the average pelvic surgeon needs to know," rather than what they already know. (*Id.* at 168:17-23). This is fully consistent with the legal standard.

The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user"

defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of person whose use is at issue in the particular case. *Johnson v. American Standard, Inc*., 179 P.3d 905, 914 (Cal. 2008) (sophisticated user "knew or should have known" of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulations say that information may be omitted from labeling: "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc*., 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd*., 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The TVT IFU says "[u]sers should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system" and that it "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)." (ETH.MESH.00875456 (attached as Ex. B)). The TVT-O IFU says it should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and

specifically in implanting the Gynecare TVT Obturator device." (ETH.MESH.02340829 (attached as Ex. C)).

So the important question with respect to the plaintiffs' failure to warn claim is what "hazards" are "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery at the time of implantation. Ethicon had no duty to warn of adverse events "commonly known" to those surgeons. Its duty was to warn of adverse events that were unique to the new devices, or, at the very least, unique to the use of the mesh in that application – surgery to treat stress urinary incontinence.

This legal standard applies regardless of whether plaintiffs point to Ethicon witnesses who have said that they believe a higher standard should apply, such as testimony by a Chief Medical Officer of the Johnson & Johnson Global Surgery Group agreeing that the IFU should include a "complete statement of what the company knows." (Ex. D, Hart Dep. Tr. 12/20/13 Dep. Tr. 800:1-8).

Internal corporate standards do not set the standard of care. *Morningstar v. Black & Decker Mfg. Co*., 253 S.E.2d 666, 368 (W.Va. 1979) ("The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made."). In fact, if they exceed the legal standard of care, they are not even admissible. *In re Tylenol (Acetaminophen) Marketing Sales Practices*, 2016 WL 807377, *8 n. 22 (E.D. Pa. March 2, 2016). The court in the Tylenol case excluded evidence of a Johnson & Johnson "Credo" because it would be against public policy to punish companies that aspired to do more than the law requires. It said:

> Allowing the company to be judged on this standard could discourage companies from creating internal policies that go beyond what the law asks. See Cast Art Indus., LLC v. KPMG LLP, 416 N.J. Super. 76, 106-07 (2010)(explaining how applying company's internal procedures with a higher standard of care than

> common-law standard could discourage companies from creating procedures that exceed common law duties), *rev'd on other grounds*, Cast Art Indus., LLC v. KPMG LLP, 209 N.J. 208 (2012); Branham v. Loews Orpheum Cinemas, Inc., 819 N.Y.S.2d 250, 255 (App. Div. 2006)("While a defendant's internal rules may be admissible as evidence of whether reasonable care was exercised, such rules must be excluded, as a matter of law, if they require a standard of care which transcends the traditional common-law standard of reasonable care under the circumstances." (citations omitted)).

Id. See also 65 C.J.S. *Negligence* § 66 (higher standard not admissible absent showing of detrimental reliance by plaintiff). Not only was it not necessary for Dr. Elser to consider internal corporate testimony to determine what surgeons commonly know, but it would have been error for her to take it into account.

What counts here is the legal standard and under that standard a manufacturer does not have a duty to warn of things likely users already know. What they know is precisely the evidence that Dr. Elser has provided.

Dr. Elser's qualifications. Dr. Elser is well-qualified to testify to what these surgeons know. She is a board certified urogynecologist. She has performed incontinence surgery since 1995. Her surgery without mesh included open and laparoscopic retropubic urethorpexies (Burch or MMK), needle suspensions, fascial bladder neck clings, injection of bulking agents, and collagen denaturation. She has also performed approximately 2,000 synthetic midurethral mesh sling surgeries. (Plaintiffs' Motion, Ex. B (General TVT & TVT-O Expert Report of Denise M. Elser, M.D.) at 1). She has used TVT since 1998 and TVT-O since 2005. (*Id.*). She has taught residents, fellows, and other surgeons how to do the surgery. (*Id.* at 1-2).

Dr. Elser also bases her opinions as to what surgeons know on a review of the medical literature, which includes articles on non-mesh surgery[1] and on mesh mid-urethral slings,[2] which

[1] *See e.g.* Plaintiff's Motion, Ex. B at 7 (study by Bergman and colleague on three different surgical procedures for incontinence), 8 (study by Weinberger and others on 108 women undergoing polytetrafluoroethylene (Gore-Tex) suburethral sling, a separate study by LeMack, GL comparing outcomes with pubovaginal sling using fascia with

are discussed in her report.[3] She also considered statements by medical professional associations, regulatory bodies, and medical education guidelines. (Plaintiff's Motion, Ex. B at 25-30). In sum, Dr. Elser does not rely on her personal experience alone.

In her opinion, surgeons already know the complications of traditional non-mesh surgery. Those complications include voiding dysfunction, permanent retention of urine, catherization, de novo urge incontinence, urinary tract infections, hernias, hematomas, fascial sling exposure, and granulomas. (*Id.* at 7-12). The Burch procedure has been shown to increase the risk of vaginal prolapse. (*Id.* at 13). It can also cause pain, sexual dysfunction and dyspareunia. (*Id.* at 36). She has operated on women with non-mesh surgery and has seen "permanent, non-reversible urgency, painful urination, incomplete bladder emptying with resultant chronic bladder infections or chronic use of [catherization]." (*Id*. at 43).

Dr. Elser says these commonly known risks are not unique to mesh surgery:

> Q: Is your opinion that with the exception of exposure all the risks listed in this new [IFU] under adverse reactions, the ones we have just been discussing, are -- are the same risks that would be in any pelvic floor surgery?

Burch urethropexy, a second separate study by Richter HE and others on a series of women undergoing a variety of fascial slings, and another prospective trial by Ostergard comparing Burch to the Lyodurasling), 9 (report published in 1996 by Kaplan and others on complications related to autologous harvest of fascia lata), 10 (the SISTEr trial published by the Urinary Incontinence Treatment Network), and 12 (study published in 1990 by Papa Petros and Ulmsten and long term data from the SISTEr trial published by Brubaker and Richter in separate articles in 2012).

[2] *See e.g.* Plaintiff's Motion, Ex. B at 13 (trial by Ward and Hilton published in 2004 comparing 344 women randomized to TVT or Burch for primary SUI and then a 5-year study by the same authors on the same women published in 2008), 14 (paper by DeLeval published in 2003 on the obturator technique for synthetic midurethral sling placement, a review from 2013 by Cox and others finding that the gold standard first-line surgical treatment for women with SUI is the synthetic midurethral sling inserted through a retropubic or transobturator approach, and a paper published by Albo in 2012 on the ToMUS trial, which compared MUS – specifically the TVT to the TVT-O and TOT), 16 (study published by Kuuva and Nilsson in 2002 on retropubic hematoma), 18 (Cochrane Review by Ogah in 2009 on minimally invasive MUS including TVT and TVT-O), 19 (paper by Cox published in 2013 on several Cochrane Review and meta-analyses showing that TVT and TVT-O are less invasive than the Burch and Fascial slings), and 20 (updated Cochrane review published by Ford in 2015 assessing the literature including RCTs and registries and finding low rates of major complications).

[3] (*See* Elser 9/16/14 Dep. Tr. 178:1 – 180:6 (testifying that her opinion on the IFU is based on training in the didactic cadaver lab, her review of the clinical literature, her membership in professional societies, and interactions with fellow physicians)).

.

> A: Okay, so foreign body response, you could have permanent sutures with foreign body response, and that could happen with any prolapse surgery. I think the only thing here unique to sling versus surgery without using mesh is that the mesh might need to be removed in its whole.
>
> But otherwise, any surgery for incontinence can have voiding dysfunction, acute or chronic pain, dyspareunia or apareunia, hemorrhage, bleeding, recurrence of incontinence…

(Ex. E, Elser 11/5/15 Dep. Tr. 80:20-81:9).

With mesh sling surgery, there are fewer wound complications than with non-mesh surgery and they are usually mesh exposures which can be conservatively managed on an outpatient basis. "[T]he only complications unique to synthetic slings are erosions and extrusions." (Plaintiff's Motion, Ex. B at 30-31). The cure rate for mesh slings is 85-90% while for the Burch procedure it is 19%. (*Id.* at 31). Dr. Elser cites to reliable literature documenting low exposure rates and that only about 1% of patients require cure by cutting the tape, which are consistent with her experience. (*Id.* at 32-35).

Based on these facts, it is her opinion that the IFUs, which specifically identify, among other things, the risks of erosion and extrusion, give adequate information to the surgeons who are the intended users:

> the IFU is adequate in providing information concerning the potential risks of the TVT and TVT-O to the intended users, namely pelvic floor surgeons who perform SUI surgery…. As pelvic floor surgeons, we know the potential risks of SUI surgery *and the only unique risk with the [midurethral sling] is mesh exposure*, although as noted earlier wound complications and suture erosions occur with non-mesh SUI surgeries.

(*Id.* at 39) (emphasis added). Although dyspareunia is not specifically mentioned, it is "a recognized risk to surgeons performing prolapse and stress incontinence surgery." (*Id.* at 42). And it is also a recognized risk of the adverse events specifically mentioned in the IFU. (Ex. C at 180:18 -181:6 (testifying that "conditions that are set forth in this IFU lead to the development of

dyspareunia" and that "dyspareunia after pelvic surgery would be known to pelvic floor surgeons"); Plaintiffs' Motion, Ex. B at 42).

This is testimony that directly addresses the appropriate legal standard, which cannot be applied without evidence of what is "commonly known" to the class of foreseeable users about the risks of the surgery. Because it is consistent with the applicable legal test, it "fits" this case whether or not Dr. Elser herself can testify to the details of that law.

Her opinion rests literature and professional association statements, not just experience. Plaintiffs do not mention a prior decision in which this Court discounted a similar attack on Dr. Elser and then rejected her testimony on other grounds. In *Bellew v. Ethicon*, this Court excluded Dr. Elser because it said her clinical experience, standing alone, was insufficient to qualify her to testify about warnings. No. 2:13-CV-22473, [Docket 265] at 33 (S.D. W. Va. Nov. 20, 2014). *See Mathison v. Boston Scientific Corp*., 2015 WL 2124991 (S.D.W.Va. 2015) at *27.

But, as is made clear by the summary of her report given above, here her testimony rests not only her own experience but on her historical review of the medical literature as well as her own experience in teaching residents, fellows in urogynecology, medical professionals and the statement of the professionals themselves through their professional associations, to which she belongs and has served on various committees as noted at pages 3-4 on her CV. This makes her well qualified to testify as to what is "commonly known" to those surgeons. This is an essential fact necessary when evaluating the "adequacy" of the IFU. Moreover, this is evidence about what is known, not evidence about what is not known, which was criticized in *Mathison*. The Court's analysis in that case leads to the conclusion that even "evidence of absence" can be established if the witness in question has in fact looked for the evidence in the right place and has

determined it does not exist, *i.e.* there is "sufficient information and investigation." Dr. Elser has certainly done that.

For these reasons, this Court's prior ruling is distinguishable and a different result should be reached here. *See Trevino v. Boston Scientific Corp.*, 2:13-CV-01617, 2016 WL 1718836, at *13-14 (S.D. W. Va. April 28, 2016).

III. Dr. Elser's design opinions have been misstated and are proper as expressed.

Plaintiffs' memorandum spends several pages belaboring Dr. Elser's lack of familiarity with certain device design protocols, all for the ostensible purpose of excluding her device design opinions. Plaintiffs try to create a technical rendition, reframing her opinion as if she was opining that Ethicon's design history documents are in proper order in defense of a claim of negligent design documentation when she has not reviewed them. This is a ruse. Dr. Elser does not give such an opinion. Her opinion pertains to the design of the device as to its functionality when implanted by the pelvic surgeon, its biocompatibility, utility, desirability and safety and efficacy as assessed by the medical literature and as compared to alternative surgical procedures to treat stress urinary incontinence. For this she is certainly qualified and her report extensively addresses the opinion and bases.

Moreover, to the extent Dr. Elser compares TVT and TVT-O surgery with non-mesh surgery, she is comparing types of surgeries, not types of device design. *Theriot v. Danek Medical Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (comparison to surgery without device is surgical issue, not design question); *Schmidt v. C.R. Bard Inc.*, 2013 WL 3802804 (D. Nev. July 22, 2013) (rejecting non-mesh surgery as an alternative design).

Dr. Elser does compare TVT and TVT-O surgery to some of plaintiffs' proposals. There she relies not only on her experience but on the medical literature – including the highest form,

the Cochrane reviews – which supports the use of TVT and TVT-O and does not support the use of untested alternatives. (Plaintiffs' Motion, Ex. B at 36-37 ("Type 1 macroporous, monofilament mesh such as the Prolene polypropylene mesh used in the TVT has the highest biocompatibility with the least propensity for infection.")). Her experience is consistent with study after study that confirm the biocompatibility of polypropylene slings:

> As a busy clinician, I … realize that there is often a vast difference between in vitro data (laboratory findings) and in vivo performance. Since the real life experience of my patients and the patients represented in study after study strongly demonstrate the biocompatibility of polypropylene slings […] plaintiffs' espoused theories regarding the weight, pore size, mechanical versus laser cut, inflammation, cytotoxicity, malignant transformation and cancer, and degradation are not scientifically reliable and contrary to the clinical data.

(*Id.* at 44. *See also id*. at 30-38 (discussing studies)). In other words, she reads the numerous clinical studies she discusses in her report to confirm the biocompatibility of mesh, and so rejects the plaintiffs' attack on biocompatibility which is not based on the same high level reliable published literature. She is fully qualified to give these opinions.[4] Plaintiffs' arguments otherwise are without merit and should be rejected.

IV. Dr. Elser is well qualified to testify regarding the safety and efficacy of TVT and TVT-O and to compare her revision rate to the ones in the literature.

Dr. Elser extensively compares in her report the safety and efficacy of TVT and TVT-O to other surgeries. After her historical review of the literature, she states in her summary:

[4] *See Trevino v. Boston Scientific Corporation*, No. 2:13:-cv-01617, 2016 WL 1718836, at *4, 5-6 (S.D. W. Va. April 28, 2016) (holding that a practicing urologist lacking design training was qualified to opine on the design of polypropylene transvaginal mesh as his "experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him in this case") (emphasis in original); *Tyree v. Boston Science Corporation*, 54 F. Supp. 3d 501, 550 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) (permitting an obstetrician and gynecologist, who had no experience in designing mesh products, to provide opine on the design of polypropylene slings as "[h]e has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products").

Based on my training, review of the literature and clinical experience, among other things, I am in agreement with the statements, analyses and guidelines reviewed above. Synthetic midurethral slings are clearly recognized as first line, gold standard and standard of care both in the United States and abroad.

I practiced medicine before synthetic midurethral slings became available. Earlier in my career, only restoration of anatomy was used, such as paravaginal repair, and compensatory defects such as Kelly plication and Burch were used to treat incontinence. I have performed many bladder neck slings. When synthetic midurethral slings were first made available, I initially used them cautiously, using MUS if only vaginal surgery was planned, and then even if abdominal hysterectomy and abdominal repair of prolapse required, I would perform a TVT vaginally for incontinence.

The reason is that slings (MUS) have the highest cure of incontinence, the most durable cure of incontinence, the least complications and are very unlikely to result in non-treatable adverse symptoms. When I reflect on women on whom I performed a bladder neck sling or a Burch, or an MMK, who ended up with permanent, non-reversible urgency, painful urination, incomplete bladder emptying with resultant chronic bladder infections, or chronic use of CISC, I am confident that I will never go back to the “old days.”

TVTs have been revolutionary in advancing the treatment of women with SUI. Further, because Burch’s and slings involved significant morbidity, in years past, women would be advised to hold off on surgical treatment until incontinence was quite severe. Because MUS are minimally invasive, with short recovery times, and low risk of serious complications, most women can opt for surgical treatment of SUI as first line therapy with markedly improved quality of life. Further, if a woman develops incomplete bladder emptying after a midurethral sling, this problem is reversible by performing a sling release. If partial or complete urinary retention occurred after a Burch or a fascial pubovesical sling, these adverse events might resolve with time, but are largely not reversible with medications nor urethrolysis. ….

In conclusion:

I completely agree with AUGS and SUFU that-

• The polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence.

> • The procedure is safe, effective, and has improved the quality of life for millions of women.
>
> • This procedure is probably the most important advancement in the treatment of stress urinary incontinence in the last 50 years.

(Plaintiffs' Motion, Ex. B at 43-44).

Plaintiffs wrongly attack Dr. Elser's ability to testify about safety and efficacy. A surgeon with her experience is allowed to examine the literature and offer such an opinion. *See Tyree*, 54 F. Supp. 3d at 585 (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures," and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D.W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit.").

Alternatively, plaintiffs focus on Dr. Elser's testimony that her practice has 4.5% sling revision rate "for either exposure or incomplete bladder emptying." (Plaintiffs' Brief at 12, *citing* Plaintiffs' Motion, Ex. B at 2). Plaintiffs complain this testimony is unverifiable because Dr. Elser could not remember the precise time period covered and number of patients included when she calculated this rate.

Elsewhere in her report, Dr. Elser gives rates from the literature. She cites a study giving a 2.7% rate for voiding dysfunction requiring surgery. (Plaintiffs' Motion, Ex. B at 15). The most recent level 1 Cochrane review gives a reoperation rate for insertion problems or voiding dysfunction of 1.6% to 2.4% with an erosion/extrusion rate of 1.5%' for TVT. (*Id.* at 20). For

TVT-O the rates were 0.8% to 2.2% and 0.4%. (*Id.* at 20-21). Other studies showed reoperation rates of 3.2%, 2.2%, 3.7%, and 3.1% (1.9% plus 1.2%). (*Id.* at 31-34).

It is unclear why plaintiffs, who do not object to her citing reoperation rates from the literature, object to her citing a slightly higher numerical rate for her personal practice. But, in any event, her personal rate is admissible and is clearly consistent with the literature. This Court has rejected nearly identical complaints from Plaintiffs before.

In *Bellew*, Plaintiffs protested that similar, clinical-experiential testimony by Dr. Stanley Robboy was improperly anecdotal. No. 2:13-CV-22473, [Docket 265] at 39-40 (S.D. W. Va. Nov. 20, 2014). Dr. Robboy correlated tissue reactions he observed in his own practice with scientific literature and concluded from there that the plaintiff had a mild tissue reaction. *Id.* at 40. Plaintiffs complained that they had no way of "independently verifying" this opinion given Dr. Robboy's reliance on his clinical (and supposedly anecdotal) experience. *Id.*

This Court gave this complaint short shrift, stating "[t]he plaintiff's argument has no practical merit." *Id.* The Court noted that "[n]umerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions" and that "[s]uch practice can hardly be described as a 'mystery'." *Id.* Recognizing the unjustified burden Plaintiffs' argument would impose, the Court emphasized that "[i]f *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions." *Id.* The Court concluded by noting that "Dr. Robboy's reference and reliance on specimens he has previously examined "demonstrate his *experience* and their typical presentation in his normal pathology practice." *Id.*[5]

[5] *See Kumho Tire Co., Ltd. V. Carmichael*, 526 U.S. 137, 156 (1999) (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience"); *Tyree*, 54 F. Supp. 3d at 585

Moreover, Plaintiffs' attempts to discredit Dr. Elser's 4.5% sling revision rate misses the mark. Dr. Elser explained at her deposition that she calculated this rate through a review of her practice's electronic medical records, which have significant amounts of data. (Elser Deposition, Nov. 5, 2015 (attached as Ex. E) at 22:17-24 (testifying that her practice has electronic medical records database with "a lot of data" on patients that have undergone mesh procedures)). In so doing, she pulled a substantial number of cases in which a sling operation was performed to see whether the patient had a reoperation within a least a year after the initial surgery. (*Id.* at 23:15-24 (testifying that "I pulled the data on a substantial number of slings in our practice and then tracked how many of those over a certain period of time went back for reoperation" and that "I believe [the period of time covered] was at least a year")).

As a result, Plaintiffs' complaints regarding her calculation are, at best, mere grist for cross-examination. Plaintiffs efforts to block Dr. Elser from testifying and relying on her own clinical experience has, as this Court has previously put it in *Bellew* (*supra* at 40), "no practical merit." Their request to exclude this testimony should therefore be denied.

CONCLUSION

Dr. Elser's distinguished and lengthy career as a board certified pelvic surgeon, using and teaching on the devices at issue, together with her extensive review of the scientific literature and many interactions with fellow colleagues qualifies her to offer the opinions at issue. Her methodology of relying on these experiences and interactions and her review of the literature in

(S.D. W. Va. 2014) (expert applied reliable methodology supporting opinion that product was safe and effective where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of the studies' he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, No. 2:13-CV-05475, 2015 WL 193111, at *12, *36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawings on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the scientific literature" to opine how these procedures compare).

reaching her conclusion is sound. The Court should enter an order denying Plaintiffs' motion to exclude certain opinions and testimony of Dr. Elser.

ETHICON, INC. AND
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on August 8, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

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